



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,880	07/28/2003	Neal L. Eigler	CEDAR.001A	3872

20995 7590 08/07/2008
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
----------	--------------

3773

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

08/07/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/628,880	Applicant(s) EIGLER ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-34 and 78-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-34 and 78-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Comment [J1]:

DETAILED ACTION

This office action is in response to claims and arguments filed 3/21/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 and 78-91 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not include "the distal portion is configured to bend at least 90 degrees."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-29, 31-34, 78-84, 86-91, 102, and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al. (US 6165183) in view of Cribier et al. (US 4777951).

Kuehn teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an elongate flexible body (108) having a proximal and a distal end; an anchor zone (441) on a distal portion of the body, and at least one tissue manipulator carried by the flexible body proximally of the anchor zone (Fig. 21); the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator (440) can be positioned at the valve (Fig. 21).
- a first and a second tissue manipulator (fig. 20).
- wherein the tissue manipulator is moveable between an axial orientation for transluminal navigation and an inclined orientation for manipulating tissue.
- wherein the first tissue manipulator (440) comprises a tissue grasper for grasping a heart valve leaflet (122).
- at least a first component (440), which is axially moveable with respect to a second component (Column 9, proximate lines 57-64)
- the catheter having a length sufficient to reach the heart from a femoral vein access
- the first and second tissue manipulators (440) are asymmetric (the graspers are not symmetric when cut in half between the proximal and

distal end), the first tissue manipulator is longer than the second tissue manipulator (see Fig. 20).

Kuehn fails to teach wherein the distal end is elongate and flexible and configured to bend at least 90 degrees to extend at least into an anatomical region adjoining the heart valve. Cribier teaches an interventional catheter for accessing the heart wherein the distal most portion is an elongate flexible anchor zone (20) which is at least about 5cm and configured to bend at least 90 degrees in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kuehn with the anchor zone of Cribier in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining.

The anchor zone of Cribier is further configured to extend from a left atrium through a mitral valve and into a left ventricular outflow tract, extend through a left ventricular outflow tract into an aorta, through a tricuspid valve and into a right ventricular outflow tract, through a right ventricular outflow tract into a pulmonary artery.

Claims 27, 32, 92-97, 99-102, and 104-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (U.S. Patent No. 5,626,588) in view of Cribier et al. (US 4777951).

Sauer teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an anchor zone (52) on a distal portion of the body, and at least one tissue manipulator carried by the body proximally of the anchor zone (88); the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator (88) can be positioned at the valve (Fig. 13).
- the elongate body comprises a fastening material (94) carried on the body for suturing two leaflets together (Fig. 13).
- there is at least one needle (58) capturing device coupled with an end of the fastening material (94).
- the fastening material (94) is at least partially housed within the tissue manipulator (Fig. 4, 58, 94, and 88).
- The fastening material (94) is at least partially located distal of the tissue manipulator when carried on the body (Fig. 4).
- The first (70) and second (72) tissue manipulators are asymmetric (Fig. 6).
- The first tissue manipulator (70) comprises a receptacle located within the first tissue manipulator (hole where 58 is located in Fig. 4) receives a first fixating member (94, Fig. 4).
- The second tissue manipulator (72) comprises a receptacle located within the second tissue manipulator (hole where 58 is located in Fig. 4) receives a first fixating member (94, Fig. 4).
- A first end of a fastening material (94) is coupled with the first receptacle (Fig. 4) and a second end of the fastening material (94) is coupled with the second receptacle (Fig. 4).

- The fastening material (94) is at least partially located distal of the tissue manipulator (Fig. 4, 94 distal of 72 and 70).
- A second needle capturing device couple with a second end fo the fastening material (Fig. 4)
- The tissue manipulator is moveable between an axial orientation for transluminal navigation and an inclined orientation for manipulating tissue (Fig. 12 and 14).

Kuehn fails to teach wherein the distal end is elongate and flexible and configured to bend at least 90 degrees to extend at least into an anatomical region adjoining the heart valve. Cribier teaches an interventional catheter for accessing the heart wherein the distal most portion is an elongate flexible anchor zone (20) which is at least about 5cm and configured to bend at least 90 degrees in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kuehn with the anchor zone of Cribier in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining.

The anchor zone of Cribier is further configured to extend from a left atrium through a mitral valve and into a left ventricular outflow tract, extend through a left ventricular outflow tract into an aorta, through a tricuspid valve and into a right ventricular outflow tract, through a right ventricular outflow tract into a pulmonary artery.

Claims 30 and 85 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kuehn and Cribier and further as a matter of design choice.

The combination of Kuehn and Cribier teaches all limitations of preceding dependent claims 27 and 82 as described previously, but fails to disclose wherein the length of anchor zone is at least about 10cm. Since applicant has not disclosed that each respective anchor zone length provides any advantage over another, and it appears that the anchor zone of the combination of Kuehn and Cribier performs the task of positioning the device at the desired location equally well as that of the application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the length of the anchor zone of the combination of Kuehn and Cribier as at least 10cm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105, USPQ 233.

Claims 98 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (U.S. Patent No. 5,626,588) and Cribier et al. (US 4777951), and further in view of Laufer et al. (U.S. Patent No. 5,609,598).

Sauer and Cribier teach the claimed invention but do not include the first tissue manipulator is longer than the second tissue manipulator (Fig. 4). It would have been obvious to one of ordinary skill in the art to have one tissue

manipulator longer than the second, as this is appropriate for the anatomy of the heart valve.

Response to Arguments

Applicant's arguments filed 3/21/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Kuehn teaches away from an anchor zone, a distally placed structure that is useful for positioning or orienting the device.
- The tip portion of Cribier is incapable of acting as an anchor zone.

Kuehn does not teach away from an anchor zone (as 440 is an anchor) or a portion distal of the anchor zone (441, Fig. 21), because Kuehn in fact teaches an anchor (441). Cribier is capable of acting as an anchor zone, the bend at the distal end of Fig. 1 is capable of acting as an anchor zone, the bend at the distal end anchors as seen in Fig. 5, as this portion anchors when the user pushes the catheter, because of the anatomy of the heart.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773